59th Medical Wing

Human Research Protection Program: Research Conflict of Interest

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Disclaimer

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Objectives

1. Define Human Research Protection Program (HRPP)
2. Describe Research Financial Conflict of Interest (FCOI)
3. Locate HRPP / COI guidance for current or prospective researchers and research staff

Training Documentation

- Completing this computer based module will serve as your 4-year HRPP/COI training which is prescribed by 59 MDWI 51-501.
- Training is required for all researchers and research staff.
- After completion:
  - Fill out, sign (digital or hand-sign) and date training certificate provided separately as a pdf (digital ok)
  - File a copy of the certificate in your research binder (this is auditable).
  - Email a copy of the certificate to the COI Office using the email address on the certificate.

Why is this important to you?

BLUF:

- It is a regulatory requirement that we provide 59 MDW HRPP / COI training for current researchers and research staff.
- ALL 59 MDW staff have a role in the Human Research Protection Program
- Everyone is responsible for protecting Human Research Subjects

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Human Research Protection Program

What is the HRPP?

It's not just the IRB

- The overarching mission of the 59 MDW Human Research Protection Program (HRPP) is to protect the rights and welfare of persons recruited to participate in research studies conducted by 59 MDW staff, including other DoD or non-DoD collaborating sites for which the 59 MDW is the IRB of Record.

- The HRPP is the foundation of our institutional culture of mutual respect and trust; ensuring the ethical conduct of research, as a shared responsibility, is conducted through cooperation, collaboration, and effective communication across the 59 MDW.

- **HRPP guiding principles:**

Respect for Persons, Beneficence, Justice…..

Reference: 59 MDWI 41-105

HRPP: What is it?

Purpose…

- To strive to adhere to the highest ethical standards in the protection of human research participants.
- To establish a formal process to monitor, evaluate and continually improve the protection of human research participants.
- To exercise oversight of research protection.
- To educate investigators and research staff about their ethical responsibility to protect research participants.
- To meet accreditation standards (i.e. Association for Accreditation of Human Research Protection Programs, The Joint Commission)

HRPP: What is it?

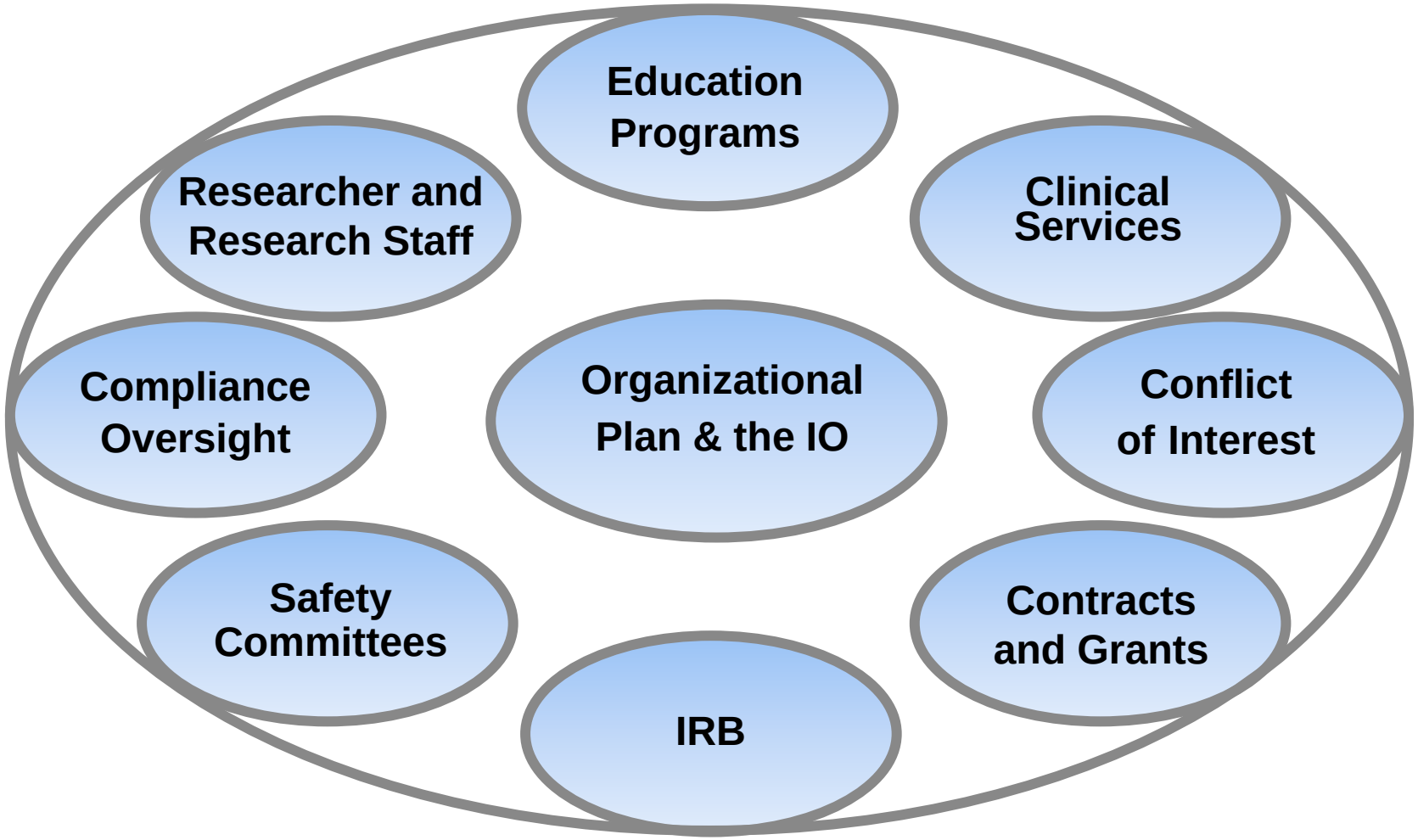
- 59 MDW HRPP is an Institutional program directed byDoDI 3216.02 15 Apr 2020
    - replaces DoDI 3216.02_AFI 40-402 which requires…
  - *“2.2. DOD COMPONENT HEADS. The heads of DoD Components that conduct or support HSR:*
    - *f. Require that all Component institutions and sub-institutions that conduct or support HSR have a Component-approved HRPP.”*

- 59 MDW HRPP guidance:
  - 59 MDWI 41-105, Human Research protection Program
  - 59 MDW HRPP OIs https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx
  - 59 MDW HRPP website http://www.59mdw.af.mil/Units/ChiefScientist-ST/HumanResearchProtectionProgram.aspx

HRPP: Who's In Charge?

- Institutional Official (IO) – Brig. Gen. Jeannine Ryder
- Authorized Institutional Official (AIO) – Dr. Debra Niemeyer
- Responsibilities
  - Oversee research administration for the 59 MDW; lead institutional research policy
  - Advocate for research in our community; promote research locally and throughout DoD
  - Create a unified program through the HRPP Steering Committee
    - HRPP Steering Committee reports to the Scientific Advisory Council (SAC) chaired by the AIO; which, in turn, reports to the 59 MDW Board of Directors (BOD) chaired by the IO

HRPP: Who is covered?



HRPP: What type of research is covered?

- All human subject research conducted on or off campus by 59 MDW assigned staff, students, or collaborators.

- Types of covered research conducted
  - Behavioral or Social Science
  - Clinical Trials
  - Epidemiological
  - Medical record/chart reviews
  - Other: pilot studies, thesis, dissertations, repositories, genetic, and information data bases

HRPP: What is covered?

Think about your research activities, consider the following…

- Does your work involve administering questionnaires, surveys, or observing a person's behavior for research purposes?
- Are you working with experiments that include health exams, changes in treatments, or the use of biologics, drugs or devices?
- Do you assist in studying groups of people or events, or the monitoring and reporting of community programs?
- Do you obtain information from a person's hospital, clinic or laboratory record for research purposes?
- Are you working with repositories for data, specimens, or genetic research?

If you answered yes to any of these questions, the HRPP policies may apply to your research….Consult the office of Clinical Investigations Research Support.

HRPP: What is covered?

Accreditation

- The Joint Commission
- AAHRPP National Accreditation (accreditation package submitted)
  - Domains
    - I: Institution/Organization – 59 MDW (Ms. Tavish)
    - II: Institutional Review Board (IRB) (Dr. Grant)
    - III: Investigator – Science & Technology (Dr. del Monaco)
- Your role in accreditation (AAHRPP, TJC)
  - Complete HRPP/COI training every 4 years
  - Know 59 MDW Human Research Protection Program (HRPP) policies
  - Be prepared for interviews during accreditation site visits
  - Know your PI responsibilities to ensure your research staff are trained

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Conflicts of Interest

What is a Conflict of Interest in Research?

- Any known financial interest, actual or potential, of a person (or their spouse, dependent child, family member) that could affect, or could reasonably appear to affect, the judgment of the researcher or a research staff member.
- Conflicts of interest often arise from financial relationships with a research sponsor or from intellectual property rights.

Why is this important?

- The 59 MDW is committed to safeguarding the public trust, to complying with all policy and statutory requirements, and preserving trust in the integrity and quality of research carried out by the investigators at the 59 MDW.

COI Examples

- Outside interests that impede proper performance of duties.
  - Serving as a paid consultant to a for-profit company at the same time you are conducting research sponsored by the company.

- Real *or perceived* interest putting into question one's objectivity or integrity when making decisions.
  - Service on a scientific advisory board for a company who is also funding your research.

- Using 59 MDW, or 59 MDW property and/or information, for personal benefit.

COI Examples

- Accepting gifts, personal loans, or favors from an individual or organization, which result from one's 59 MDW position
- Disclosing information to individuals or organizations which afford them an advantage not generally available to others
- Placing oneself under obligation to any person who might benefit from special consideration or favor, or who might seek preferential treatment, advice, service, or consultation

59 MDW COI Policy

- Who is subject to the disclosure policy?
- What must be disclosed?
- When must disclosure be made?
- Where (how) must interests be disclosed?

COI: Who must disclose?

- The Primary Investigator (PI), project director and/or any other person, *regardless of title or position*, who is responsible for project design, conduct of research or reporting human subjects research findings must disclose.
  - A research project is any systematic investigation designed to develop or contribute to generalizable knowledge that involves a 59 MDW employee or other person where the 59 MDW *is responsible for the oversight and/or administration of the activity.*
- 59 MDW/ST Key Personnel, all individuals, and their family members, who are conducting research are responsible for knowing, understanding, and complying with this 59 MDW COI policy.

COI: What to disclose?

What must be disclosed?

- Significant Financial Interests (SFI)
  - Remuneration from public and/or non-publicly traded entities that, when aggregated, are > $5,000 over the last 12 months
  - *Any* equity in a non-publicly traded entity
  - A position in an entity related to the research
  - Intellectual Property and/or royalties
  - Reimbursed or sponsored travel (other than from a federal agency)
    - Gifts of travel having a market value > $20 per source per occasion
    - Gifts from a single source with an aggregate market value exceeding $50 in a calendar year

COI: What to disclose?

- **The term significant financial interest does NOT include:**
  (*partial list, refer to 59 MDW 51-501 and 59 MDW Forms 14 and 15*)
  - Salary royalties or other remuneration paid by the institution
  - Income from investment vehicles, such as mutual funds and regiment accounts, which the person has no direct control over
  - Income or travel reimbursement from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency
  - For active duty and government employees an off duty employment application is required

*59 MDW FORM 51-501

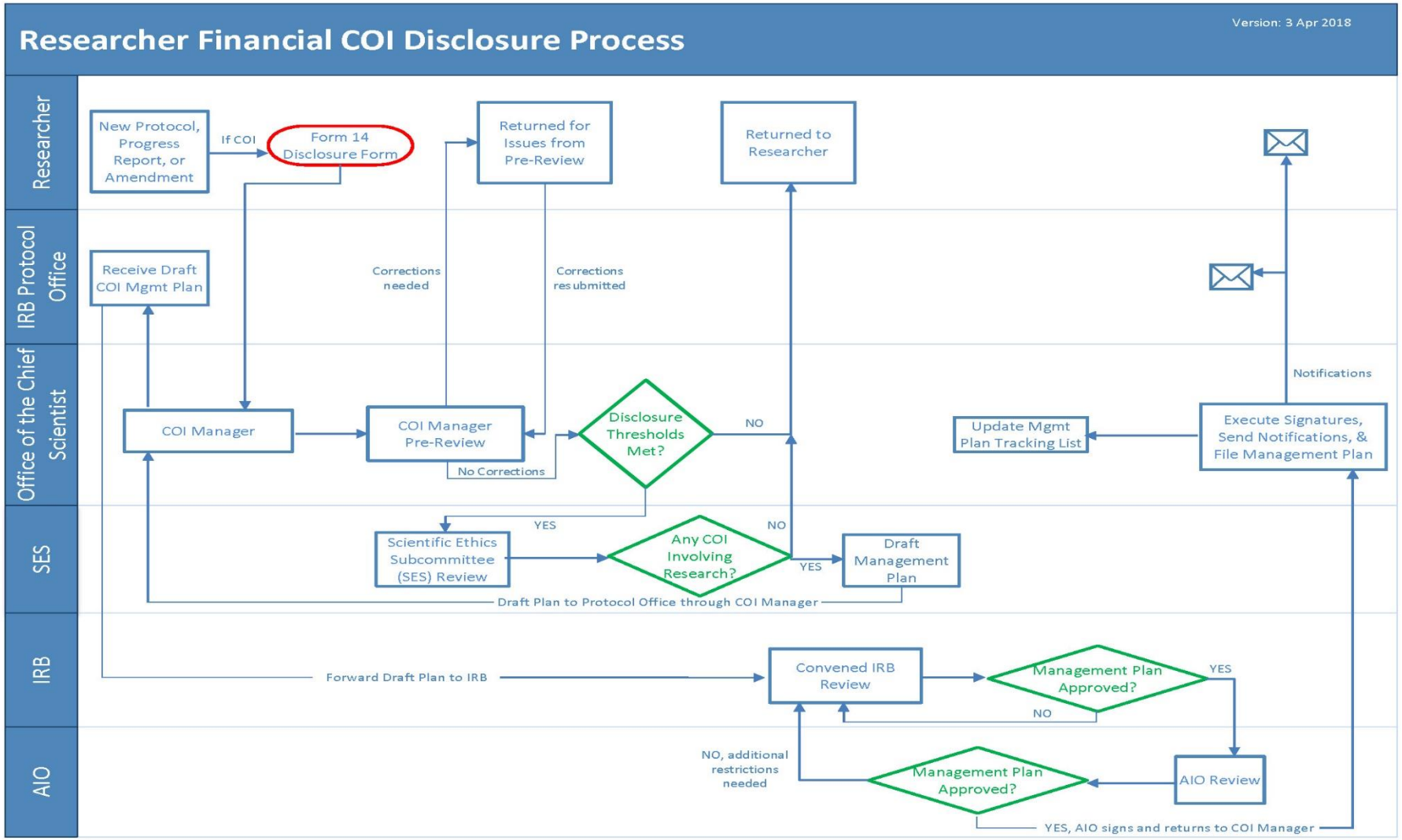
static.e-publishing.af.mil/production/1/59mdw/publication/59mdwi51-501/59mdwi51-501.pdf

COI: When to disclose?

When to disclose significant financial COI (FCOI)

- **BEFORE** beginning the research when you have indicated a potential FCOI on your protocol template
- Annually update during the life of your study
- Any change to the status of the conflict must be reported to the COI Manager and IRB within 30 days of discovery
- As part of the new and continuing review process, the PI must attest that ALL collaborators (study personnel)
  - Either have no COI or have no COI changes or
  - All changes have been provided to the COI office

COI Disclosure Process for Researchers



COI: Disclosure Process

- The conflicted individual will download, complete, encrypt, and email FORM 14 to 59 MDW COI Office

  (see 59 MDW FORM 14 for instructions)

- COI Manager reviews whether there is a significant financial COI

- If a conflict exists, the Scientific Ethics Sub-committee (SES) is consulted
  - SES is a sub-committee chartered by the Scientific Advisory Committee (SAC) for the purpose of working with the PI to develop a Research FCOI Management Plan

COI: Disclosure Process

- The SES will use the following evaluation criteria when considering a request by an individual with a FCOI regarding conduct of research involving human subjects
  - The nature of the research
  - Magnitude of the interest and degree to which it is related to the research
  - Extent to which the interest could be directly/substantially affected by the research
  - The degree of risk to involved that is inherent in research protocol
  - Extent to which the interest is amendable to effective oversight and management
  - Whether the individual is uniquely qualified by virtue of expertise and experience such that the research could not otherwise be conducted safely or effectively without the individual.

COI: Disclosure Process

- FCOI Management Plan (MP)
  - The conflicted Team Member works with the COI Manager and the Scientific Ethics Subcommittee to develop a management plan using a simple template

- FCOI Management Controls *(not a comprehensive list)*
  - Investigator may be precluded from obtaining informed consent
  - Disclosure of interest included in the Informed Consent
  - Independent data reviewer assigned
  - “Safe harbor” for students
  - External monitoring conducted
  - Second-Level Review required

COI: Disclosure Process

- FCOI Management Plan
  - The management plan that has been developed with the Scientific Ethics Subcommittee is submitted with the protocol for IRB review
    - If the IRB requires changes, the management plan will be coordinated by the COI manager with the SES and the PI
- The final Financial COI Management Plan will be filed and tracked by the COI manager

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HRPP / COI Guidance

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- Resources
  - Research Reference Guide (Principal Investigator's Handbook): http://www.59mdw.af.mil/Units/ChiefScientist-ST/HumanResearchProtectionProgram.aspx
  - 59 MDW IRB FAQS https://kx2.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/FAQ.aspx
- Websites:
  - Chief Scientist / S&T http://www.59mdw.af.mil/Units/ChiefScientist-ST.aspx
  - 59 MDW HRPP http://www.59mdw.af.mil/Units/ChiefScientist-ST/HumanResearchProtectionProgram.aspx
  - 59 MDW CIRS https://kx2.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx
- Documents:
  - DoDI 3216.02 - Protection of Human Subjects and Adherence to Ethical Standards in DoD Conducted and Supported Research (15 April 2020)
  - 59 MDWI 51-501 - Managing Conflict of Interest in Research, Forms 14/15
  - 59 MDWI 41-105 - Human Research Protection Program

59th Medical Wing contacts

Helpful Contacts/ Phone Numbers

- 59 MDW Chief Scientist /ST Main Office
  (210) 292-2097 (DSN 554)
- CIRS Protocol Office (210) 292-4683
- HRPP Research Compliance Office (210) 292-5146
- COI Office (210) 292-5885

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